

# **EXHIBIT A**

IN THE CIRCUIT COURT TWENTIETH JUDICIAL CIRCUIT

ST. CLAIR COUNTY, ILLINOIS

ANNE M. KLENE and RICHARD T.  
KLENE,

Plaintiffs,

v.

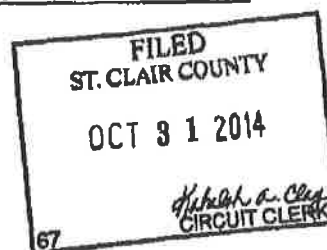
BOSTON SCIENTIFIC CORPORATION,  
BOSTON SCIENTIFIC SALES, INC.,  
MENTOR WORLDWIDE, L.L.C.,  
JOHNSON & JOHNSON, INC. and  
JOHNSON & JOHNSON SERVICES,  
INC.,

Defendants.

NO. 14-L-

723

PLAINTIFFS DEMAND TRIAL  
BY JURY



PLAINTIFFS' COMPLAINT

COMES NOW the Plaintiffs, by and through their attorneys, Michael L. McGlynn and McGlynn & McGlynn, and for their Complaint against the Defendants, states:

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1. Plaintiffs, Anne M. Klene and Richard T. Klene, are citizens of the State of Illinois, and reside in Belleville, in the County of St. Clair, Illinois. Plaintiff, Anne M. Klene, had one or more of Defendants' pelvic mesh products inserted in her body to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence; Anne M. Klene underwent several procedures involving transvaginal mesh including:

03/24/04 Transobturator Tape, Obtape, procedure;

08/18/10 Transobturator Tapes (TOT), Obtryx mesh;

12/10/10 partial removal, excision;

02/16/11 exploration involving ObTape vaginal mesh with excision of Obtryx mesh; involving Boston Scientific pubovaginal sling known as Obtryx and ObTape introduced by Mentor Corporation, later acquired by Johnson & Johnson.

**DEFENDANTS**

2. Defendant Boston Scientific Corporation., is a corporation organized and existing under the laws of the State of Delaware. Defendant, Boston Scientific Corporation is the parent company of Boston Scientific Sales, Inc. At all times relevant to this action, Defendant Boston Scientific Corporation. has conducted business in the County of St. Clair, State of Illinois, with its principal place of business located at One Boston Scientific Place, Natick, MA. 01760. Boston Scientific Corporation's registered agent for service of process is Corporation Service Company, 84 State Street, Boston, MA. 02109.

3. Defendant Boston Scientific Sales, Inc. is a subsidiary of Boston Scientific Corporation. At all times relevant to this action, Defendant has conducted business in the County of St. Clair, State of Illinois, with its principal place of business located at One Boston Scientific Place, Natick, MA. 01760. Boston Scientific Sales, Inc's registered agent for service of process is C.T. Corporation System, 155 Federal Street, Suite 700, Boston, MA. 02110.

4. Defendant Mentor Worldwide, LLC, is a Limited Liability Company. At all times relevant to this action, Defendant Mentor Worldwide, LLC. has conducted business in the County of St. Clair, State of Illinois, with its principal place of business located at 5425 Hollister Avenue, Santa Barbara, CA. 93111. Mentor Worldwide, LLC's registered agent for service of process is The Corporation Company, Marietta, GA. 30060; this Defendant was recently acquired by Johnson & Johnson, Inc.

5. Defendant Johnson & Johnson, Inc., is a corporation organized and existing under the laws of the State of New Jersey. Defendant Johnson & Johnson, Inc. is the parent company of Johnson & Johnson Services, Inc. At all times relevant to this action, Defendant Johnson & Johnson, Inc. has conducted business in the County of St. Clair, State of Illinois, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, N.J. 08933. Johnson & Johnson, Inc.'s registered agent for service of process is Douglas K. Chin.

6. Defendant Johnson & Johnson Services, Inc. is a corporation organized and existing under the laws of the State of New Jersey. Defendant Johnson & Johnson Services, Inc. is a subsidiary of Johnson & Johnson, Inc. At all times relevant to this action, Defendant Johnson & Johnson Services, Inc. has conducted business in the County of St. Clair, State of Illinois, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, N.J. 08933. Johnson & Johnson, Inc.'s registered agent for service of process is Douglas K. Chin.

#### VENUE

7. Plaintiffs are at all times residents of St. Clair County, Illinois. Defendants do business in St. Clair County, Illinois.

#### FACTUAL BACKGROUND

8. Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal tissue.

9. Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

10. Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

11. The scientific evidence shows that the material from which Defendants' Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including Anne M. Klene.

12. Defendants omitted the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients.

13. The specific nature of the Products' defects includes, but is not limited to the following:

- a. the use of polypropylene and collagen material in the Products and the immune reactions that result from such material, causing adverse reactions and injuries;
- b. the design of the Products to be inserted transvaginally into and through an area of the body with high levels of bacteria that can adhere to the mesh

- causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
- c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury.
  - d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;
  - e. the propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;
  - f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking;
  - g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;
  - h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;
  - i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

- j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;
- k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;
- l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions;
- m. the procedure itself, which is part of Defendants' Pelvic Mesh Products, requires the physician to insert the device "blindly" resulting in nerve damage and damage to other internal organs;
- n. the design of trocars, as devices which as part of Defendants' Pelvic Mesh Products and which are used to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

14. The Products are also defective due to Defendants' failure to adequately warn or instruct Plaintiff, Anne M. Klene.

15. Defendants have underreported information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media. Defendants have also underreported information about the injuries caused by the use of the implantation kits and surgical technique instructions that accompany their pelvic meshes.

16. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

17. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

### **CAUSES OF ACTION**

#### **COUNT I – NEGLIGENCE**

18. Paragraphs 1 – 17 of this Complaint are hereby incorporated by reference as if fully set forth herein.

19. Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

20. As a direct and proximate result of Defendants' negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

#### **COUNT II – STRICT LIABILITY – DESIGN DEFECT**

21. Plaintiffs incorporate paragraphs 1 - 20 as if fully set forth herein.

22. As a direct and proximate result of the Products' aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

#### **COUNT III – FRAUDULENT CONCEALMENT**



23. Plaintiffs incorporate by reference paragraphs 1 – 22 of this Complaint as if fully set forth herein.

24. On October 20, 2008, the Food and Drug Administration (“FDA”) issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as “adverse events”) that had been reported over a three year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA’s MAUDE database indicates that the Defendants are one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products are “rare.”

25. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

- a) Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants’ Pelvic Mesh Products;
- b) Defendants knowingly made false claims about the safety and quality of the Defendants’ Pelvic Mesh Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and
- c) Defendants fraudulently and affirmatively concealed the defective nature of the Defendants’ Pelvic Mesh Products from Plaintiffs.

26. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants’ Pelvic Mesh Products.

27. At all times herein mentioned, Defendants, and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians, and therefore, Plaintiffs, with the intent to defraud as herein alleged.

28. As a direct and proximate result of this conduct, Plaintiffs were injured.

**COUNT IV – DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT**

29. Plaintiffs incorporate by reference paragraphs 1 -28 of this Complaint as if fully set forth herein.

30. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

31. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

32. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the Products.

**COUNT V – LOSS OF CONSORTIUM**

33. Plaintiffs incorporate by reference paragraphs 1 -32 of this Complaint as if fully set forth herein.

34. As a direct and proximate result of the above-described injuries sustained by Anne M. Klene in the Complaint, where applicable, her spouse, Richard T. Klene, has suffered a loss of spousal consortium, companionship, society, affection, services and support.

**COUNT VI – PUNITIVE DAMAGES**

35. Plaintiffs incorporate by reference paragraphs 1 – 34 of this Complaint as if fully set forth herein.

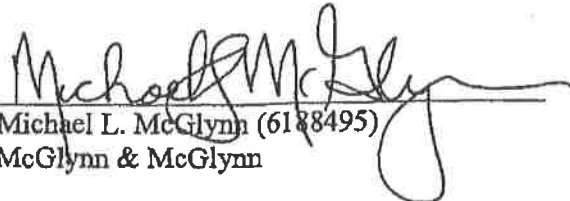
36. Defendants withheld material information from the medical community and the public in general, including the female Plaintiff.

37. Defendants knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

38. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, in an amount in excess of \$50,000.00, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

Respectfully submitted,

  
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